JUN - 8 2011

510(k) Summary

K111339

Date Prepared June 8, 2011

Submitter

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Establish Registration Number: 2184009

Contact Person

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Device Name and Classification

Trade Name:	Hemostasis Management System Plus (HMS Plus)
Common Name:	Automated Heparin Analyzer
Regulation Number:	21 CFR 864.5680
Product Code:	JOX
Classification:	Class II

Predicate Device

HMS Plus (K101271 – Cleared October 13, 2010)

Comparison to Predicate Device

A comparison of the modified device and the currently marketed HMS Plus show the following similarities:

- Same intended use.
- Same operating principle.
- Same technological characteristics.
- Same performance claims.

Description of Device Modification and the Reasons for Implementation

ADS – Hantronix HMS Plus PCBA

Hardware modifications addressed in this submission are a direct response to the obsolescing of several major hardware components including the Print Circuit Board, the ADU Controller and the Printer. The HMS software has also been modified to run on Windows CE 5.0. A complete system verification and software verification of all requirements have been performed. The Display Adapter Hantronix PCBA and Power Interconnect PCBA have been incorporated into the Interface PCBA to reduce interconnects and have a more reliable device.

HMS Plus ADU Controller PCBA

The Common Processing Platform has been used to replace the Freescale HC11. A complete ADU software verification of all requirements has been performed.

HMS Plus Printer

A new Printer has been selected that will work with the new Off the Shelf Computer PCBA. The voltage of the printer has been reduced from 24 V to 7V.

HMS Plus Labeling

The Operators Manual and Device labels have been updated to reference the IEC 61010-1: 2001, 2nd Edition standard.

Intended Use

The HMS Plus instrument is a microprocessor based, multichannel clot timing system with automated syringe handling for pipetting blood into single use cartridges. It performs in vitro heparin sensitivity evaluations, heparin assays, and activated clotting times.

Conclusion

The modifications to the HMS Plus described in this submission result in a substantially equivalent device because the fundamental scientific technology and the intended use are unchanged.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

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Re: k111339
Trade/Device Name: Hemostasis Management System Plus (HMS Plus)
Regulation Number: 21 CFR 864.5680
Regulation Name: Automated Heparin Analyzer
Regulatory Class: Class II
Product Code: JOX
Date: May 11, 2011
Received: May 13, 2011

Dear Ms. Racic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of

substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111339

Device Name: **Hemostasis Management System Plus (HMS Plus)**

Indications for Use:

The HMS Plus instrument is a microprocessor based, multichannel clot timing system with automated syringe handling for pipetting blood into single use cartridges. It performs in vitro heparin sensitivity evaluations, heparin assays, and activated clotting times.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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